



FEI: 3003194366

Food and Drug Administration
Central Region
Baltimore District Office
6000 Metro Drive, Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5454
FAX: (410) 779-5707

WARNING LETTER

04-BLT-19

April 28, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Edward D. Purich, Ph.D.
President/CEO
ChiRhoClin, Inc.
4000 Blackburn Lane
Suite 270
Burtonsville, MD 20866

Dear Dr. Purich:

During the period of February 9 through 13, 2004, the Food and Drug Administration (FDA) conducted an inspection of your firm located at 4000 Blackburn Lane, Burtonsville, MD to determine your firm's compliance with the Postmarketing Adverse Drug Experience (PADE) reporting requirements of Sections 505(k) of the Federal Food, Drug, and Cosmetic Act ("the Act"), and Title 21, Code of Federal Regulations (CFR), Part 314.

Based on our review of the inspection report, we conclude that your firm violated Section 301 (e) of the Act because it failed to comply with 21 CFR Part 314 and Section 505 (k) (1) of the Act.

Deviations from the PADE regulations include, but are not limited to the following:

1. Failure to develop adequate written procedures for the surveillance and receipt of postmarketing adverse drug experiences [21 CFR 314.80 (b)]. Specifically, none of the firm's written standard operating procedures (SOPs) outline steps related to the surveillance and receipt of postmarketing adverse drug experiences (ADE) reports (oral or written) handled by [REDACTED], which is the marketing and distributing firm which you have contracted for the initial collection of ADE reports for your firm. None of your firm's written ADE SOPs included procedures on how your firm performs surveillance and tracks reports handled by [REDACTED]. In addition, none of your ADE SOPs included procedures on how ADE reports were to be received from [REDACTED].

2. Failure to submit all quarterly periodic adverse drug experience reports for Secreflo™, NDA 21-136, approved April 4, 2002 within 30 days of the close of the quarter [21 CFR 314.80 (c) (2)]. Specifically,

<u>Quarter Starting/Closing</u>	<u>Submission Due</u>	<u>Date on Quarterly Report Submitted to FDA</u>
1. October 2002-December 2002	January 30, 2003	February 26, 2003
2. January 2003-March 2003	April 30, 2003	May 14, 2003

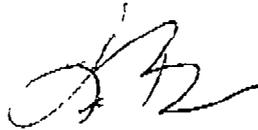
Neither the above list of deviations nor the Form FDA 483 "Inspection Observations" which was presented to you at the completion of this inspection is intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure adherence to each requirement of the Act and its regulations. The FDA expects drug manufacturers to establish reasonable procedures to assure that all adverse drug experiences are recorded, evaluated, and submitted to the FDA within established timeframes as required by 21 CFR 314.80.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action by FDA without further notice. These actions include, but are not limited to, seizure and/or injunction. Federal Agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted deviations and to prevent their recurrence. Your response should address the comments listed above and include examples of documentation showing that corrections have been achieved. If corrective action can not be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be directed to Randy F. Pack, Compliance Officer, Food and Drug Administration, Baltimore District Office, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215. If you have any questions, please do not hesitate to contact Mr. Randy F. Pack at (410) 779-5454, extension 417.

Sincerely,



Lee Bowers,
District Director